

RECEIVED
CENTRAL FAX CENTER

JUN 16 2006

TRANSMITTAL OF APPEAL BRIEF		Docket No. (Optional): 50508-1030																																				
<p>I hereby certify that this correspondence is being transmitted via facsimile to the United States Patent and Trademark Office, facsimile number 571-273-8300, on the date indicated below:</p> <p><u>June 16, 2006</u> Total pages: <u>47</u></p> <p>Date</p> <p><u>Rhonda Zaffino</u></p> <p>Signature – Rhonda Zaffino</p>		<p>In re Application of Roback et al.</p> <table border="1"> <tr> <td>Application Number 09/773,826</td> <td>Filed 01/31/2001</td> </tr> <tr> <td colspan="2">For Immunological Assay System and Method</td> </tr> <tr> <td>Group Art Unit 1743</td> <td>Examiner Latoya I. Cross</td> </tr> <tr> <td colspan="2">Confirmation No.: 7152</td> </tr> </table>	Application Number 09/773,826	Filed 01/31/2001	For Immunological Assay System and Method		Group Art Unit 1743	Examiner Latoya I. Cross	Confirmation No.: 7152																													
Application Number 09/773,826	Filed 01/31/2001																																					
For Immunological Assay System and Method																																						
Group Art Unit 1743	Examiner Latoya I. Cross																																					
Confirmation No.: 7152																																						
<p>Transmitted herewith is the Appeal Brief in this application with respect to the Notice of Appeal filed on January 17, 2006</p> <p>The fee for this Appeal Brief is (37 CFR 1.17(c) \$ 250.00</p> <p style="text-align: center;">(complete (a) or (b) as applicable)</p> <p>The proceedings herein are for a patent application and the provisions of 37 CFR 1.17(a)-(d) apply.</p> <p><input checked="" type="checkbox"/> (a) Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)-(d) for the total number of months checked below:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 60%;">One month (37 CFR 1.17(a)(1))</td> <td style="width: 25%; text-align: right;">\$ 60.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Two months (37 CFR 1.17(a)(2))</td> <td style="text-align: right;">\$ 215.00</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Three months (37 CFR 1.17(a)(3))</td> <td style="text-align: right;">\$ 490.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Four months (37 CFR 1.17(a)(4))</td> <td style="text-align: right;">\$ 765.00</td> </tr> <tr> <td colspan="3"> <input type="checkbox"/> The extension fee has already been filed in this application.</td> </tr> <tr> <td colspan="3"> <input type="checkbox"/> (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that the applicant has inadvertently overlooked the need for a petition and fee for extension of time.</td> </tr> <tr> <td colspan="3"> Method of Payment:</td> </tr> <tr> <td colspan="3"><input checked="" type="checkbox"/> Payment is enclosed as follows:</td> </tr> <tr> <td colspan="3"><input type="checkbox"/> A check in the amount of _____ enclosed.</td> </tr> <tr> <td colspan="3"><input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached in the amount of \$740.00</td> </tr> <tr> <td colspan="3"><input type="checkbox"/> The Commissioner is authorized to charge _____ to a Deposit Account</td> </tr> <tr> <td colspan="3"><input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any deficiencies in fees, or credit any overpayment to Deposit Account No. 20-0778. A duplicate copy is enclosed.</td> </tr> </table> <p>Warning: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p><u>06/16/06</u> <u>Cynthia J. Lee</u></p> <p>Date Cynthia J. Lee, Reg. No. 46,033</p>			<input type="checkbox"/>	One month (37 CFR 1.17(a)(1))	\$ 60.00	<input type="checkbox"/>	Two months (37 CFR 1.17(a)(2))	\$ 215.00	<input checked="" type="checkbox"/>	Three months (37 CFR 1.17(a)(3))	\$ 490.00	<input type="checkbox"/>	Four months (37 CFR 1.17(a)(4))	\$ 765.00	 <input type="checkbox"/> The extension fee has already been filed in this application.			 <input type="checkbox"/> (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that the applicant has inadvertently overlooked the need for a petition and fee for extension of time.			 Method of Payment:			<input checked="" type="checkbox"/> Payment is enclosed as follows:			<input type="checkbox"/> A check in the amount of _____ enclosed.			<input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached in the amount of \$740.00			<input type="checkbox"/> The Commissioner is authorized to charge _____ to a Deposit Account			<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any deficiencies in fees, or credit any overpayment to Deposit Account No. 20-0778. A duplicate copy is enclosed.		
<input type="checkbox"/>	One month (37 CFR 1.17(a)(1))	\$ 60.00																																				
<input type="checkbox"/>	Two months (37 CFR 1.17(a)(2))	\$ 215.00																																				
<input checked="" type="checkbox"/>	Three months (37 CFR 1.17(a)(3))	\$ 490.00																																				
<input type="checkbox"/>	Four months (37 CFR 1.17(a)(4))	\$ 765.00																																				
 <input type="checkbox"/> The extension fee has already been filed in this application.																																						
 <input type="checkbox"/> (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that the applicant has inadvertently overlooked the need for a petition and fee for extension of time.																																						
 Method of Payment:																																						
<input checked="" type="checkbox"/> Payment is enclosed as follows:																																						
<input type="checkbox"/> A check in the amount of _____ enclosed.																																						
<input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached in the amount of \$740.00																																						
<input type="checkbox"/> The Commissioner is authorized to charge _____ to a Deposit Account																																						
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any deficiencies in fees, or credit any overpayment to Deposit Account No. 20-0778. A duplicate copy is enclosed.																																						

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED
CENTRAL FAX CENTER

In Re Application of:

Roback, et al.

Confirmation No.: 7152

JUN 16 2006

Serial No.: 09/773,826

Art Unit: 1743

Filed: January 31, 2001

Examiner: Cross, Latoya I.

For: Immunological Assay System
And Method

Atty. Docket No.: 050508-1030

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This Appeal Brief under 37 C.F.R. § 41.37 is submitted in support of the Notice of Appeal filed January 17, 2006, responding to the Final Office Action mailed September 20, 2005.

It is not believed that extensions of time or fees are required to consider this Appeal Brief. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to Deposit Account No. 20-0778.

06/19/2006 LWONDIM1 00000052 200778 09773826
01 FC:2402 250.00 0P

*Application Serial No. 09/773,826
Art Unit: 1743*

I. Real Party in Interest

The real party in interest is Emory University, a non-profit corporation established under the laws of the State of Georgia and having a principal place of business at Office of Technology, 1784 North Decatur Road, Suite 130, North Decatur Building, First Floor, Atlanta, Georgia 30322, U.S.A. (hereinafter "Emory").

II. Related Appeals and Interferences

There are no known related appeals or interferences that will affect or be affected by a decision in this Appeal.

III. Status of Claims

Claims 5, 7, 10, and 29 have been canceled, and claims 12-24 have been withdrawn from consideration, leaving claims 1-4, 6, 8, 9, 11, and 25-28 remaining pending and under consideration. Each of those claims stands finally rejected. No claims have been allowed. The final rejections of claims 1-4, 6, 8, 9, 11, and 25-28 are appealed.

IV. Status of Amendments

This application was originally filed on January 31, 2001, with twenty-nine (29) claims. In a Response filed October 14, 2003, Applicants elected with traverse to prosecute claims 1-11 and 25-29. In a Response filed May 10, 2004, Applicants amended claims 1 and 25 and canceled claims 10 and 29. In a Response filed November 11, 2004, Applicants amended claims 1 and 25 and canceled claim 11. In a Response filed January 25, 2005, Applicants amended claims 1, 11

Application Serial No. 09/773,826
Art Unit: 1743

and 25. On June 24, 2005, Applicants amended claims 1, 4, 11, and 25 and canceled claims 5 and 7.

All of the above-identified amendments have been entered and no other amendments have been made to any of claims 1-4, 6, 8, 9, 11, and 25-28. The claims in the attached Claims Appendix (see below) reflect the present state of those claims.

V. Summary of Claimed Subject Matter

The claimed inventions are summarized below with reference numerals and references to the written description ("specification") and drawings. The subject matter described in the following appears in the original disclosure at least where indicated, and may further appear in other places within the original disclosure.

Independent claim 1 describes an immunological assay system. The system of claim 1 comprises a filter vessel capable of containing an assay sample of red blood cells, white blood cells, or platelets, wherein the filter vessel comprises a filter material chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane, the filter material including a plurality of pores with a pore size from about 3 microns to about 5 microns. *See Specification* at page 4, line 29 – page 5, line 11 and page 7, line 26 – page 8, line 2.

The system of claim 1 further comprises an incubator in which the filter vessel may be placed, wherein the incubator houses the filter vessel while the assay sample and one or more reagent antibodies react. *See Specification* at page 5, lines 19-21 and page 6, lines 1-6.

The system of claim 1 further comprises a sample separation system in close proximity to the incubator, wherein the sample separation system is designed to separate the mixture of the

Application Serial No. 09/773,826
Art Unit: 1743

assay sample and the reagent antibodies into various components. *See Specification* at page 5, lines 19-23 and page 6, lines 7-15.

The system of claim 1 further comprises an image acquisition system in close proximity to the sample separation system, wherein the image acquisition system consists of a flow cytometer, the flow cytometer being designed to detect the presence of interactions between reagent antibodies and the assay sample cells, wherein said interactions are evidenced by at least one of agglutinations and antigen-antibody interactions. *See Specification* at page 5, lines 19-24 and page 6, lines 16-26.

The system of claim 1 further comprises a robotic pipettor including a robotic arm within reaching distance of the filter vessel, the incubator, the sample separation system and the image acquisition system, wherein the robotic pipettor is designed to transfer the assay sample or the reagent antibodies between the filter vessel, incubator, the sample separation system and the image acquisition system. *See Specification* at page 5, lines 19-26 and page 6, line 27 – page 7, line 2.

Independent claim 11 describes an immunological assay system. The system of claim 11 comprises a filter vessel capable of containing an assay sample comprising patient antibody samples, wherein the filter vessel comprises a filter material chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane, the filter material including a plurality of pores with a pore size from about 0.1 microns to about 3 microns. *See Specification* at page 4, line 29 – page 5, line 11 and page 7, line 28 – page 8, line 2.

The system of claim 11 comprises an incubator in which the filter vessel may be placed, wherein the incubator houses the filter vessel while the assay sample and one or more reagent

Application Serial No. 09/773,826
Art Unit: 1743

cells react, wherein the reagent cells are antigen carriers and are chosen from at least one of the following: red blood cells, white blood cells, and platelets. *See Specification* at page 5, lines 19-21 and page 6, lines 1-6.

The system of claim 11 comprises a sample separation system in close proximity to the incubator, wherein the sample separation system is designed to separate the mixture of the assay sample and reagent cells into various components. *See Specification* at page 5, lines 19-23 and page 6, lines 7-15.

The system of claim 11 comprises an image acquisition system in close proximity to the sample separation system, wherein the image acquisition system consists of a camera, the camera being configured to detect the presence of interactions between the reagent cells and the assay sample antibodies, wherein said interactions are evidenced by at least one of agglutinations and antigen-antibody interactions. *See Specification* at page 5, lines 19-24 and page 6, lines 16-26.

The system of claim 11 comprises a robotic pipettor including a robotic arm within reaching distance of the filter vessel, the incubator, the sample separation system and the image acquisition system, wherein the robotic pipettor is designed to transfer the assay sample or the reagent cells between the filter vessel, incubator, the sample separation system and the image acquisition system. *See Specification* at page 5, lines 19-26 and page 6, line 27 – page 7, line 2.

Independent claim 25 describes an immunological assay system. The system of claim 25 comprises a filter means, wherein the filter means is chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane, the filter means including a plurality of pores with a pore size from about 0.1 microns to about 3 microns. *See Specification*, e.g., at page 4, line 29 – page 5, line 11 and page 7, line 26 – page 8, line 2.

*Application Serial No. 09/773,826
Art Unit: 1743*

The system of claim 25 comprises means for incubating in the filter means antibodies and antigen carriers, wherein the antigen carriers are chosen from at least one of the following: red blood cells, white blood cells, and platelets. *See Specification, e.g., at page 5, lines 19-21 and page 6, lines 1-6.*

The system of claim 25 comprises means for separating the agglutinated antigen carriers or reacted antibodies and antigen carriers from fluid containing the unreacted antibodies or antigen carriers in the filter means into components above and below. *See Specification, e.g., at page 5, lines 19-23 and page 6, lines 7-15.*

The system of claim 25 comprises a flow cytometer configured to analyze the components above or below, or both above and below the filter, wherein the flow cytometer is also configured to determine the presence of interactions between the antibodies and antigen carriers, wherein said interactions are evidenced as at least one of aggregated components and antigen-antibody interactions. *See Specification, e.g., at page 5, lines 19-24 and page 6, lines 16-26.*

Application Serial No. 09/773,826
Art Unit: 1743

VI. Grounds of Rejection to be Reviewed on Appeal

The following grounds of rejection are to be reviewed on appeal:

1. Claims 1, 2-6, 8, 11 and 25-27 are rejected under 35 U.S.C 103(a) as being unpatentable over U.S. Patent No. 5,620,898 to Yaremko et al. ("Yaremko") in view of U.S. Patent No. 5,308,990 to Takahashi et al. ("Takahashi") and U.S. Patent No. 6,182,834 to Kim et al. ("Kim").

2. Claims 9 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al. ("Yaremko"), Takahashi et al. ("Takahashi"), and Kim et al. ("Kim"), as applied above, and further in view of U.S. Patent No. 5,603,899 to Franciskovich et al. ("Franciskovich").

VII. Arguments

The Appellant respectfully submits that Applicants' claims are not obvious under 35 U.S.C. § 103, and respectfully request that the Board of Patent Appeals overturn the final rejections of those claims at least for the reasons discussed below.

Preliminary Matter

The present application claims priority to a U.S. provisional patent application Serial No. 60/179,248. A corresponding Patent Cooperation Treaty (PCT) patent application was filed on the same day as the instant application, also claiming priority to the same provisional patent application Serial No. 60/179,248. Applicants wish to note that the corresponding PCT patent

Application Serial No. 09/773,826
Art Unit: 1743

application received a favorable International Preliminary Examination Report (IPER), a copy of which is attached hereto as Exhibit "A." As noted in the IPER, the PCT Examining Authority has determined that the claims of the PCT patent application (a copy of which also appears in Exhibit "A") are novel and contain an inventive step over the prior art.

Applicants also wish to note that the European Patent Office (EPO) has since examined the claims of the corresponding PCT patent application at the national phase, and the EPO has also determined that the claims of that patent application are novel and involve an inventive step over the prior art. After making procedural amendments to the European Patent Application, a Notice of Allowance is expect to be forthcoming. A copy of the first Official Action from the EPO is attached hereto as Exhibit "B."

Even though the standards for patentability in the PCT process and before the EPO may differ slightly from the USPTO, Applicants believe that the fact that both the PCT Examining Authority and the EPO have found the corresponding patent application both novel and to involve an inventive step is persuasive of the novelty and nonobviousness of the instant claims.

As a final note, the material portions of the file history of the corresponding PCT patent application has been filed in an Information Disclosure Statement (IDS), which is required to be considered by the Examiner. The references contained in the International Search Report of the PCT patent application have already been submitted by Applicants on August 6, 2001 and initialed as considered by Examiner in January 2004.

Claim Rejections – 35 USC §103

I. Claims 1, 2-6, 8, 11, and 25-27 are rejected under 35 U.S.C 103(a) as being unpatentable over U.S. Patent No. 5,620,898 to Yaremko et al. ("Yaremko") in view of U.S. Patent No.

Application Serial No. 09/773,826
Art Unit: 1743

5,308,990 to Takahashi et al ("Takahashi") and U.S. Patent No. 6,182,834 to Kim et al. ("Kim").

Claim 5 has been canceled, and thus rejection of this claim is moot. Applicants respectfully traverse the rejection of the remaining claims.

As has been acknowledged by the Court of Appeals for the Federal Circuit, the U.S. Patent and Trademark Office ("USPTO") has the burden under section 103 to establish a *prima facie* case of obviousness by showing some objective teaching in the prior art or generally available knowledge of one of ordinary skill in the art that would lead that individual to the claimed invention. *See In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). The Manual of Patent Examining Procedure (MPEP) section 2143 discusses the requirements of a *prima facie* case for obviousness. That section provides as follows:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure.

In the present case, the prior art at least does not teach or suggest all of the claim limitations, as will be demonstrated in the following.

A. Independent Claim 1

The Office Action has rejected claim 1 as allegedly unpatentable over the combination of *Yaremcio* in view of *Takahashi* and *Kim*. For at least the reasons that follow, Applicants respectfully disagree and request that the rejection be overturned.

Application Serial No. 09/773,826
Art Unit: 1743

Independent claim 1 recites:

1. An immunological assay system, comprising:
 - a filter vessel capable of containing *an assay sample of red blood cells, white blood cells, or platelets, wherein the filter vessel comprises a filter material chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane, the filter material including a plurality of pores with a pore size from about 3 microns to about 5 microns*;
 - an incubator in which the filter vessel may be placed, wherein the incubator houses the filter vessel while the assay sample and one or more *reagent antibodies* react;
 - a sample separation system in close proximity to the incubator, wherein the sample separation system is designed to separate the mixture of the assay sample and the reagent antibodies into various components;
 - an image acquisition system in close proximity to the sample separation system, wherein *the image acquisition system consists of a flow cytometer, the flow cytometer being designed to detect the presence of interactions between reagent antibodies and the assay sample cells*, wherein said interactions are evidenced by at least one of agglutinations and antigen-antibody interactions; and
 - a robotic pipettor including a robotic arm within reaching distance of the filter vessel, the incubator, the sample separation system and the image acquisition system, wherein the robotic pipettor is designed to transfer the assay sample or the reagent antibodies between the filter vessel, incubator, the sample separation system and the image acquisition system.

(Emphasis added). Applicants respectfully submit that independent claim 1 defines over the combination of *Yaremko* in view of *Takahashi* and *Kim* for at least the reason that the combination fails to teach the features emphasized above.

Specifically, the cited references (including *Kim*) fail to teach or suggest the feature of "wherein the filter vessel comprises a filter material chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane, the filter material including a plurality of pores with a pore size from about 3 microns to about 5 microns." The Office Action admits that *Yaremko* and *Takahashi* do not teach the filter materials of independent claim 1 and instead

Application Serial No. 09/773,826
Art Unit: 1743

relies on *Kim* as allegedly providing this feature of the independent claims. *See Final Office Action of September 20, 2005* at 3.

The filter material of *Kim* is a non-woven material. *See Kim* at col. 3, lines 52-60. Although some of the non-woven fibers of *Kim* overlap with some of the fibers of the claims, the filter materials of the instant claims are not directed to non-woven fabrics. Instead, the instant claims recite fabrics that are woven, or some other type of material than non-woven (which is a specific type of material). For example, attached as "Exhibit C" are print-outs of web pages from websites of companies that supply filter materials of the type recited in claim 1 (e.g., "polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate"). In particular, included is a print-out from the website of Sefar, Inc., which is disclosed in the specification as providing filter materials that can be used in the claimed invention. As can be seen from the material in Exhibit C, each of the types of fabric of claim 1 is clearly not the non-woven material of *Kim*. The term "non-woven" or "nonwoven" is a specific term of art for a particular type of fabric. Attached hereto as "Exhibit D" is a printout from the *Merriam-Webster Online Dictionary*, which defines the term "nonwoven" as "made of fibers held together by interlocking or bonding (as by chemical or thermal means)." This does not encompass the filter materials of claim 1.

There are numerous advantages for using the specific filter materials of claim 1, as outlined in the material of Exhibit C. In addition, the use of the woven materials is non-obviousness because Applicants have discovered that the roughened topography of the woven filter materials of claim 1 prevents reagents from clumping up when centrifuged.

Application Serial No. 09/773,826
Art Unit: 1743

Therefore, the cited combination of references does not teach or suggest all features of independent claim 1. For at least this reason, Applicants respectfully request that the rejection of these claims be reconsidered and withdrawn.

Notwithstanding the forgoing allowability of claim 1, the Office Action admits that *Yaremko* and *Takahashi* do not teach the filter pore size of the claim 1, but instead relies on *Kim* as allegedly supplying this feature. *See Final Office Action of September 20, 2005* at 3. Applicants respectfully traverse.

Kim recites a filter material with a pore size of not more than 3 microns. *See Kim* at col. 3, lines 52-60. Independent claim 1 recites a pore size of 3-5 microns for the filter material. Thus, this is an additional non-obvious distinction of claim 1 over the cited references. Applicants therefore respectfully request that the rejection of claim 1 be withdrawn for at least this reason as well.

In addition, *Yaremko* fails to teach or suggest the recited feature of claim 1 of "flow cytometer being designed to detect the presence of interactions between reagent antibodies and the assay sample cells" and the assay sample including "red blood cells, white blood cells, or platelets." Indeed, the Office admits this by stating, "*Yaremko* et al. differs from the instant invention in that it teaches a camera to image the analysis results, whereas Applicants claim the use of a flow cytometer." *Office Action of March 25, 2005* at 4. *Takahashi* fails to cure this deficiency. The portion of *Takahashi* relied on by the Office, col. 1, lines 37-53, discloses the following:

On the other hand, as an immunological measurement method using particles, there is known a method, by which *antigen concentration is measured by making latex spheres, with the surface of which an antibody is bound*, react with an antigen and *measuring the agglutinated state of the latex spheres* produced by the antigen-antibody reaction by the absorbance or the intensity of scattered light. Further, in order to analyze this agglutinated state with a high

Application Serial No. 09/773,826
Art Unit: 1743

precision, there is known also a method, by which each agglutinated lump is led to a flow cytometer to be analyzed there. By this method it is possible to calculate the magnitude of each agglutinated lump, based on the intensity of scattered light to measure the antigen concentration with a high precision...

(*Emphasis added*). Thus, the disclosure of *Takahashi* is limited to measuring the agglutinated state of latex spheres to which antibodies are bound. Essentially, *Takahashi* simply describes using a flow cytometer to count the latex beads. Nothing in *Takahashi* teaches or suggests detecting interactions of a patient assay sample and reagent antibodies that are not bound to latex spheres.

Not only is *Takahashi* limited to measuring agglutinated state of latex spheres (not antigen-red blood cell interactions, *e.g.*, as in the independent claims), but *Takahashi* does not require filter materials since their assays do not require separation of cells from fluid. The filter of the independent claims is of a pore size the filters cellular components from fluid.

In addition, Applicants respectfully submit that the combination of *Yaremko* with *Takahashi* is improper. *Yaremko* is directed to an automated blood analysis system, whereas *Takahashi* is directed to a method and instrument "for measuring microparticles capable of detecting microparticles having a very low fluorescence intensity existing in liquid...." *Id.* at col. 1, lines 8-11 (*emphasis added*). The field of immunological testing is very broad. One searching for a solution to any problems of *Yaremko* would not look for answer in *Takahashi* because *Takahashi* is directing to detecting microparticles having an inherent fluorescence. In addition, it does not teach filtration or the use of filters to prepare cells for this process. Nowhere does *Yaremko* teach or suggest detecting microparticles having an inherent fluorescence. Thus, these two references are directed to very different aspects of the broad field of immunological testing. Further, *Kim* does not cure these deficiencies of *Yaremko* and *Takahashi*. Indeed, the term "flow cytometer" does not appear anywhere in the *Kim* reference.

Application Serial No. 09/773,826
Art Unit: 1743

For at least these reasons, as well as the reasons recited above, Applicants respectfully submit that the combination of *Yaremko* in view of *Takahashi* and *Kim* does not render claim 1 obvious, and request that the rejection of claim 1 be withdrawn.

B. Independent Claim 11

The Office Action of March 25, 2005 rejected claim 11 on the same identical bases as claim 1 (see Office Action of March 25, 2005, pages 3-4). The undersigned respectfully submits that such a rejection is inappropriate, as the two claims are not coextensive in scope. However, for purposes of this Appeal Brief, and in an effort to focus on other issues in this Appeal Brief, the undersigned submits that claim 11 patently defines over the cited art for at least some of the same reasons discussed above in connection with claim 1. In this regard, claim 11 includes the features of "a filter material chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane", which is not taught or suggested by the cited references, as noted above with respect to claim 1.

Further, claim 11 recites "wherein the image acquisition system consists of a camera, the camera being configured to detect the presence of interactions between the reagent cells and the assay sample antibodies." This feature is not taught or suggested by the *Yaremko* and *Takahashi* references for at least the same reasons cite above with respect to the flow cytometer of claim 1. Additionally, *Kim* does not cure these deficiencies of *Yaremko* and *Takahashi*. Indeed, the term "camera" does not appear anywhere in the *Kim* reference.

For at least these reasons, as well as the reasons recited above, Applicants respectfully submit that the combination of *Yaremko* in view of *Takahashi* and *Kim* does not render claim 11

Application Serial No. 09/773,826
Art Unit: 1743

obvious, and request that the rejection of claim 11 be overturned.

C. Independent Claim 25

The Office Action rejected claim 25 on the same identical bases as claim 1 (see Office Action, pages 3-4). The undersigned respectfully submits that such a rejection is inappropriate, as the two claims are not coextensive in scope. Although there are distinctions between claims 25 and claim 1, the filter means of claim 25 is chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane, and the filter means includes a plurality of pores with a pore size from about 0.1 microns to about 3 microns, similar to a corresponding elements of claims 1 and 11. As noted above, these features are not taught or suggested by the recited references.

In addition, claim 25 recites a flow cytometer that is "configured to determine the presence of interactions between the antibodies and antigen carriers." As noted above, *Yaremko* does not disclose a flow cytometer in its system. *Takahashi* discloses a flow cytometer that analyzes the agglutinated state of *latex spheres* to which antibodies are bound. Thus, using a flow cytometer to measure only naturally occurring cellular components, as claimed in claim 25, is not taught or suggested by the combination of cited references. Further, *Kim* does not cure these deficiencies of *Yaremko* and *Takahashi* as the term "flow cytometer" does not appear anywhere in the *Kim* reference.

For at least these reasons, as well as the reasons recited above, Applicants respectfully submit that the combination of *Yaremko* and *Takahashi* does not render claim 25 obvious, and request that the rejection of claim 25 be overturned.

Application Serial No. 09/773,826
Art Unit: 1743

D. Dependent Claims 2-4, 6, 8-9, and 26-28

Because independent claims 1 and 25 are allowable, then for at least the reason that their dependent claims contain all the features of their respective independent claim, dependent claims 2-4, 6, 8-9, and 26-28 are also allowable. Applicants therefore respectfully request that the rejection of these claims be overturned as well.

Claims 9 and 28

Claims 9 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al. ("Yaremko"), Takahashi et al. ("Takahashi"), and Kim et al. ("Kim") as applied above and further in view of U.S. Patent 5,603,899 to Franciskovich et al. ("Franciskovich").

If independent claims 1 and 25 are allowable, then dependent claims 9 and 28 are also allowable for at least the same reason since they incorporate all of the features of their respective independent claims.

*Application Serial No. 09/773,826
Art Unit: 1743*

VIII. Conclusion

In summary, it is Applicants' position that Applicants' claims are patentable over the applied prior art references and that the rejection of these claims should be withdrawn. Appellant therefore respectfully requests that the Board of Appeals overturn the Examiner's rejection and allow Applicants' pending claims.

Respectfully submitted,

By: Cynthia J. Lee
Cynthia J. Lee
Registration No. 46,033

Application Serial No. 09/773,826
Art Unit: 1743

Claims Appendix under 37 C.F.R. § 41.37(c)(1)(viii)

The following are the claims that are involved in this Appeal.

1. (Previously Presented) An immunological assay system, comprising:
 - a filter vessel capable of containing an assay sample of red blood cells, white blood cells, or platelets, wherein the filter vessel comprises a filter material chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane, the filter material including a plurality of pores with a pore size from about 3 microns to about 5 microns;
 - an incubator in which the filter vessel may be placed, wherein the incubator houses the filter vessel while the assay sample and one or more reagent antibodies react;
 - a sample separation system in close proximity to the incubator, wherein the sample separation system is designed to separate the mixture of the assay sample and the reagent antibodies into various components;
 - an image acquisition system in close proximity to the sample separation system, wherein the image acquisition system consists of a flow cytometer, the flow cytometer being designed to detect the presence of interactions between reagent antibodies and the assay sample cells, wherein said interactions are evidenced by at least one of agglutinations and antigen-antibody interactions; and
 - a robotic pipettor including a robotic arm within reaching distance of the filter vessel, the incubator, the sample separation system and the image acquisition system, wherein the robotic pipettor is designed to transfer the assay sample or the reagent antibodies between the filter vessel, incubator, the sample separation system and the image acquisition system.

*Application Serial No. 09/773,826
Art Unit: 1743*

2. (Original) The system of claim 1, further comprising a washer, wherein the washer is designed to wash the assay sample while the sample is disposed within the filter vessel.
3. (Original) The system of claim 1, wherein the filter vessel comprises a filter including an inert material including a plurality of pores.
4. (Previously Presented) The system of claim 3, wherein the filter vessel is configured to hold the assay sample such that the assay sample comes into contact with the filter material.
5. (Canceled)
6. (Original) The system of claim 3, wherein the filter material has a thickness between approximately three microns and approximately five millimeters.
7. (Canceled)
8. (Original) The system of claim 1, wherein the sample separation system is a centrifuge.
9. (Original) The system of claim 1, wherein the sample separation system is a vacuum system.
10. (Canceled)

Application Serial No. 09/773,826
Art Unit: 1743

11. (Previously Presented) An immunological assay system, comprising:

- a filter vessel capable of containing an assay sample comprising patient antibody samples, wherein the filter vessel comprises a filter material chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane, the filter material including a plurality of pores with a pore size from about 0.1 microns to about 3 microns;
- an incubator in which the filter vessel may be placed, wherein the incubator houses the filter vessel while the assay sample and one or more reagent cells react, wherein the reagent cells are antigen carriers and are chosen from at least one of the following: red blood cells, white blood cells, and platelets;
- a sample separation system in close proximity to the incubator, wherein the sample separation system is designed to separate the mixture of the assay sample and reagent cells into various components;
- an image acquisition system in close proximity to the sample separation system, wherein the image acquisition system consists of a camera, the camera being configured to detect the presence of interactions between the reagent cells and the assay sample antibodies, wherein said interactions are evidenced by at least one of agglutinations and antigen-antibody interactions; and
- a robotic pipettor including a robotic arm within reaching distance of the filter vessel, the incubator, the sample separation system and the image acquisition system, wherein the robotic pipettor is designed to transfer the assay sample or the reagent cells between the filter vessel, incubator, the sample separation system and the image acquisition system.

12. (Withdrawn) An immunological assay method comprising the steps of:

- incubating an immunological sample and reagent mixture in a filter vessel;
- separating the sample and reagent mixture in the filter vessel into components above and below a filter; and
- analyzing the components above or below, or both above and below, the filter in the filter vessel to determine the presence of interactions between the components.

*Application Serial No. 09/773,826
Art Unit: 1743*

13. (Withdrawn) The method of claim 12, further comprising the step of transferring the filter vessel to a turntable mechanism after the separating step, but before the analyzing step.

14. (Withdrawn) The method of claim 12, further comprising:
a first step of placing a sample in a filter vessel, wherein the sample comprises cellular components;
a second step of adding antibody reagents to the sample; and
wherein the step of separating the sample and reagent mixture comprises separating the sample mixture into cellular components and liquid components, and
wherein the step of analyzing the filter vessel comprises analyzing the cellular components that remain above the filter.

15. (Withdrawn) The method of claim 12, further comprising:
a first step of placing a sample in a filter vessel, wherein the sample comprises antibody containing samples such as plasma or serum;
a second step of adding antigen carrier reagents, such as red blood cells or synthetic beads, to the antibody containing sample; and
wherein the step of separating the sample and reagent mixture comprises separating the sample mixture into antigen carrier components and liquid components, and
wherein the step of analyzing the filter vessel comprises analyzing the antigen carrier components that remain above the filter.

*Application Serial No. 09/773,826
Art Unit: 1743*

16. (Withdrawn) The method of claim 15, wherein the step of analyzing the filter vessel produces unclear results, and further comprising the steps of:

separating the antigen carrier components from the liquid components by capturing the antigen carrier components above the filter in the filter vessel;

washing the components above the filter with a physiological salt solution;

separating the antigen carrier components from the liquid components;

adding antibody reagents to the washed antigen carrier components remaining above the filter in the filter vessel;

incubating the antigen carrier components and the antibody reagents in the filter vessel;

separating the sample and reagent mixture in the filter vessel into components above and below the filter;

washing the antigen carrier components above the filter with a physiological salt solution;

and

analyzing the components above or below the filter in the filter vessel to determine the presence of interactions between the components.

17. (Withdrawn) The method of claim 16, wherein the washing step comprises the steps of:

providing a physiological salt solution selected from the group consisting of saline, phosphate buffered saline and other physiological salt solutions which preserve the viability of the cellular components during the assay;

adding between approximately 10 microliters to approximately 5 milliliters of the physiological salt solution the sample;

separating the sample into the antigen carrier components remaining above the filter from the liquid components below the filter; and

repeating the adding and separating steps from one to approximately ten times.

18. (Withdrawn) The method of claim 12, wherein the step of placing an immunologic assay sample in a filter vessel comprises placing an immunologic assay sample in a filter vessel comprising a filter including an inert material including a plurality of pores.

*Application Serial No. 09/773,826
Art Unit: 1743*

19. (Withdrawn) The method of claim 12, wherein the step of separating the sample and reagent mixture in the filter vessel into components above and below the filter comprises the step of separating the sample and reagent mixture with a centrifugation system.
20. (Withdrawn) The method of claim 19, wherein the step of separating the sample and reagent mixture with a centrifugation system comprises separating the sample and reagent mixture with a centrifugation system operating at a speed between approximately 10 X g and approximately 10,000 X g.
21. (Withdrawn) The method of claim 19, wherein the step of separating the sample and reagent mixture with a centrifugation system comprises separating the sample and reagent mixture with a centrifugation system operating for a time between approximately five seconds and approximately five minutes.
22. (Withdrawn) The method of claim 12, wherein the step of separating the sample and reagent mixture in the filter vessel into components above and below the filter comprises the step of separating the sample and reagent mixture with a vacuum system.
23. (Withdrawn) The method of claim 22, wherein the step of separating the sample and reagent mixture with a vacuum system comprises separating the sample and reagent mixture with a vacuum system operating at a pressure of between approximately - 0.1 inches Hg to approximately - 100 inches Hg.
24. (Withdrawn) The method of claim 12, wherein the step of analyzing the components above or below the filter comprises analyzing the components with a flow cytometer.

Application Serial No. 09/773,826
Art Unit: 1743

25. (Previously Presented) An immunological assay system comprising:
 - a filter means, wherein the filter means is chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane, the filter means including a plurality of pores with a pore size from about 0.1 microns to about 3 microns;
 - means for incubating in the filter means antibodies and antigen carriers, wherein the antigen carriers are chosen from at least one of the following: red blood cells, white blood cells, and platelets;
 - means for separating the agglutinated antigen carriers or reacted antibodies and antigen carriers from fluid containing the unreacted antibodies or antigen carriers in the filter means into components above and below; and
 - a flow cytometer configured to analyze the components above or below, or both above and below the filter, wherein the flow cytometer is also configured to determine the presence of interactions between the antibodies and antigen carriers, wherein said interactions are evidenced as at least one of aggregated components and antigen-antibody interactions.
26. (Original) The system of claim 25, wherein the filter means is a filter vessel.
27. (Original) The system of claim 25, wherein the means for separating the sample and reagent mixture is a centrifuge.
28. (Original) The system of claim 25, wherein the means for separating the sample and reagent mixture is a vacuum system.
29. (Canceled)

Application Serial No. 09/773,826
Art Unit: 1743

Evidence Appendix under 37 C.F.R. § 41.37(c)(1)(ix)

Attached hereto are Exhibits "A" and "B", which Applicants submitted in the "Third Response to Office Action (With Amendments), Submission Pursuant to 37 CFR 1.114(c)" on January 25, 2005. Applicants' submission was deemed entered by the Examiner in an Office Action mailed March 25, 2005.

In addition, according to 37 C.F.R. § 41.33(d)(1):

an affidavit or other evidence filed after the date of filing an appeal...may be admitted if the examiner determines that the affidavit or other evidence overcomes all rejections under appeal and that a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented has been made.

Accordingly, Applicants submitted a "Response After Final Office Action" on January 17, 2006 in which Exhibits "C" and "D", attached hereto were included (labeled as "Exhibit A" and "Exhibit B," respectively, in said Response After Final Office Action of January 17, 2006). The Examiner in the instant case has given no indication whether the Exhibits were entered or not into the record. Exhibits C and D were provided in response to the rejections presented in the final Office Action of September 20, 2005 and therefore they could not have been previously presented. Upon consideration of the Exhibits C and D, the rejection of the claims 1, 2-6, 8, 11, and 25-27 based upon a combination of other references with *Kim* (U.S. Patent No. 6,182,834) should be withdrawn. Therefore, Applicants respectfully request that the Board consider Exhibits C and D.

*Application Serial No. 09/773,826
Art Unit: 1743*

Related Proceedings Appendix under 37 C.F.R. § 41.37(c)(1)(x)

There are no related proceedings to be considered in this Appeal. Therefore, no such proceedings are identified in this Appendix.

00382989

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US01/03206

Re Item V

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

Reference is made to the following document:

D1: DE 41 24 778 A (UNIV SCHILLER JENA) 28 January 1993 (1993-01-28)

1. Document D1 (see especially col 2, II 30-57 and Examples) discloses an immunological assay system comprising a plurality of filter vessels (1-6), an incubator in which the filter vessel may be incubated while sample and reagents react (not explicitly described, but incubation is mentioned as a process step, e.g. at col 3, I 55), a sample separation system (microtitre plate 8,14 and centrifuge or pipetter, cf. col 2, II 52-57), an image acquisition system (reader, col 3, I 62) and a robotic pipetter (cf. e.g. col 4, II 24-29).

The assay system of claim 1 differs from this closest state of the art in that the image acquisition system is designed to optically analyse and detect the presence of interactions in the assay mixture above the filter plate in the filter vessel. Document D1 only discloses the optical analysis of the filtrate, below the filter plate. The same applies to the system according to independent claim 25, and to the methods according to independent claims 12, 15 and 16, each of which includes the step of optically analysing and detecting the presence of interactions in the assay mixture above the filter plate in the filter vessel.

Consequently, independent claims 1, 12, 15, 16 and 25 satisfy the requirement of novelty (Art 33(1) and (2) PCT).

2. The other documents cited in the international search report disclose apparatus and methods used in automatic assays involving filter plates. None of these documents discloses or suggests the step of optically analysing and detecting the presence of interactions in the assay mixture above a filter plate in a filter vessel in an assay system.

Consequently, the independent claims 1, 12, 15, 16 and 25 are also considered to

INTERNATIONAL PRELIMINARY EXAMINATION REPORT - SEPARATE SHEET International application No. PCT/US01/03206

satisfy the requirement of inventive step (Art 33(1) and (3) PCT).

3. Dependent claims 2-11, 13, 14, 17-24 and 27-29 relate to particular embodiments of the systems and methods of the new and inventive independent claims, and consequently also satisfy the requirements of Article 33 PCT.

CLAIMS

Now, therefore, the following is claimed:

1. An immunological assay system, comprising:
 - a filter vessel having a filter plate, wherein the filter vessel is capable of containing an assay sample;
 - an incubator in which the filter vessel may be placed, wherein the incubator houses the filter vessel while the assay sample and one or more reagents react;
 - a sample separation system in close proximity to the incubator, wherein the sample separation system is designed to separate the assay sample and the reagents into various components;
 - an image acquisition system in close proximity to the sample separation system and filter vessel, wherein the image acquisition system is designed to optically analyze and detect the presence of interactions between the components and reagents of the assay mixture above the filter plate in the filter vessel; and
- 15 a robotic pipettor including a robotic arm within reaching distance of the filter vessel, the incubator, the sample separation system and the image acquisition system, wherein the robotic pipettor is designed to transfer the sample or the reagents between the filter vessel, incubator, the sample separation system and the image acquisition system.
- 20 2. The system of claim 1, further comprising a washer, wherein the washer is designed to wash the assay sample while the sample is disposed within the filter vessel.
3. The system of claim 1, wherein the filter vessel comprises a filter including an inert material including a plurality of ports.
4. The system of claim 3, wherein the filter vessel is configured to hold an assay sample such that the sample comes into contact with the filter material.

REPLACEMENT PAGE 13

Empfangszeit 20.Juni 21:35



Amended claims



EXHIBIT A
PAGE 32/47

5. The system of claim 3, wherein the pores of the filter material comprise a size between approximately 0.01 micron and approximately 50 microns.

REPLACEMENT PAGE 13.1

Empfangszeit 20.Juni 21:35

85

Amended claims

EXHIBIT A
PAGE 4 OF 9

6. The system of claim 3, wherein the filter material has a thickness between approximately three microns and approximately five millimeters.
7. The system of claim 3, wherein the filter material is selected from the group consisting of: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane.
8. The system of claim 1, wherein the sample separation system is a centrifuge.
9. The system of claim 1, wherein the sample separation system is a vacuum system.
10. The system of claim 1, wherein the image acquisition system is a flow cytometer.
11. The system of claim 1, wherein the image acquisition system is a camera.
- 10 12. An immunological assay method comprising the steps of: incubating an immunological sample and reagent mixture in a filter vessel; separating the sample and reagent mixture in the filter vessel into components above and below a filter plate; and optically analyzing the components above the filter plate in the filter vessel to determine the presence of interactions between the components.
- 15 13. The method of claim 12, further comprising the step of transferring the filter vessel to a turntable mechanism after the separating step, but before the analyzing step.

REPLACEMENT PAGE 14

Empfangszeit 20.Juni 21:35

29

Amended claims

EXHIBIT A
PAGE 34/47

14. The method of claim 12, further comprising:

a first step of placing a sample in a filter vessel, wherein the sample comprises cellular components;

5 a second step of adding antibody reagents to the sample; and

wherein the step of separating the sample and reagent mixture comprises separating the sample mixture into cellular components and liquid components, and

wherein the step of analyzing the filter vessel comprises analyzing the cellular components that remain above the filter.

15. An immunological assay method comprising the steps of:

10 a first step of placing a sample in a filter vessel having a filter plate, wherein the sample comprises antibody containing samples such as plasma or serum;

a second step of adding antigen carrier reagents, such as red blood cells or synthetic beads, to the antibody containing sample;

15 incubating an immunological sample and reagent mixture in a filter vessel;

separating the sample and reagent mixture in the filter vessel into components above and below the filter plate, wherein the step of separating the sample and reagent mixture comprises separating the sample mixture into antigen carrier components and liquid components; and

20 optically analyzing the components above the filter plate in the filter vessel to determine the presence of interactions between the components, wherein the step of analyzing the filter vessel comprises analyzing the antigen carrier components that remain above the filter.

REPLACEMENT PAGE 15

Empfangszeit 20.Juni 21:35

Amended claims

EXHIBIT A
PAGE 6 OF 9

16. An immunological assay method comprising the steps of:
 - a first step of placing a sample in a filter vessel having a filter plate, wherein the sample comprises antibody containing samples such as plasma or serum;
 - a second step of adding antigen carrier reagents, such as red blood cells or synthetic beads, to the antibody containing sample;
 - incubating an immunological sample and reagent mixture in a filter vessel;
 - separating the sample and reagent mixture in the filter vessel into components above and below the filter plate, wherein the step of separating the sample and reagent mixture comprises separating the sample mixture into antigen carrier components and liquid components; and
 - optically analyzing the components above the filter plate in the filter vessel to determine the presence of interactions between the components, wherein the step of optically analyzing the filter vessel comprises analyzing the antigen carrier components that remain above the filter, and wherein the following additional steps are performed if the step of optically analyzing the components above the filter plate produces unclear results:
 - separating the antigen carrier components from the liquid components by capturing the antigen carrier components above the filter in the filter vessel;
 - washing the components above the filter with a physiological salt solution;
 - separating the antigen carrier components from the liquid components;
 - adding antibody reagents to the washed antigen carrier components remaining above the filter in the filter vessel;
 - incubating the antigen carrier components and the antibody reagents in the filter vessel;
 - separating the sample and reagent mixture in the filter vessel into components above and below the filter;
 - washing the antigen carrier components above the filter with a physiological salt solution; and

REPLACEMENT PAGE 16

Empfangszeit 20.Juni 21:35

SEN

Amended claims

Patent Application

EXHIBIT A
PAGE 7 OF 9

optically analyzing the components above or below the filter in the filter vessel to determine the presence of interactions between the components.

17. The method of claim 16, wherein the washing step comprises the steps of:
 - providing a physiological salt solution selected from the group consisting of
 - 5 saline, phosphate buffered saline and other physiological salt solutions which preserve the viability of the cellular components during the assay;
 - adding between approximately 10 microliters to approximately 5 milliliters of the physiological salt solution the sample;
 - separating the sample into the antigen carrier components remaining above the
 - 10 filter from the liquid components below the filter; and
 - repeating the adding and separating steps from one to approximately ten times.

REPLACEMENT PAGE 16.1

Empfangszeit 20.Juni 21:35

Amended claims

EXHIBIT A
PAGE 8 OF 9

25. An immunological assay system comprising:
 - a filter vessel having a filter plate;
 - means for incubating a sample and reagent mixture in the filter vessel;
 - means for separating the sample and reagent mixture in the filter vessel into components above and below the filter plate; and
 - means for optically analyzing the components in the filter vessel above the filter plate to determine the presence of interactions between the sample and the reagent in the filter vessel.
27. The system of claim 25, wherein the means for separating the sample and reagent mixture is a centrifuge.
28. The system of claim 25, wherein the means for separating the sample and reagent mixture is a vacuum system.
29. The system of claim 25, wherein the means for analyzing the components above or below, or both above and below the filter is a flow cytometer.

REPLACEMENT PAGE 18

Empfangszeit 20.Juni 21:35

Amended claims

EXHIBIT A
PAGE 9 OF 9

Beschaff/Protokoll (Anlage)	Communication/Minutes (Annex)	Notification/Procès-verbal (Annexe)
Datum Date Date 01.04.2004	Blatt Sheet Feuille 1	Anmelde-Nr.: Application No: 01 903 454.5 Demande n°:

The examination is being carried out on the following application documents:

Text for the Contracting States:

AT BE CH LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR

Description, pages:

1-13 as originally filed

Claims, No.:

1-25,27-29 as originally filed

Drawings, sheets:

1/3-3/3 as originally filed

Comments:

* Claims 1-17,25 and 27-29 as amended during the PCT-II procedure

1. Although no objection to the novelty and inventive step of the claims was raised in the IPER, a number of formal objections need to be resolved to bring the application into order for grant:

1.1 Claims 1 and 25 in the apparatus category and 12,15 and 16 in the method category have been drafted as separate independent claims.

Under Article 84 in combination with Rule 29(2) EPC an application may contain more than one independent claim in a particular category only if the subject matter claimed falls within one or more of the exceptional situations set out in paragraphs (a), (b) or (c) of Rule 29(2) EPC. This is not the case in the present application however. The claims should be restricted to a single independent claim in each category, with dependent claims as appropriate.

EXHIBIT B
PAGE 1 OF 2

Beschluß/Protokoll (Anlage)	Communication/Minutes (Annex)	Notification/Procès-verbal (Annexe)
Datum Date Datum 01.04.2004	Blatt Sheet Feuille 2	Anmelde-Nr: Application No.: 01 903 454.5 Demande n°:

1.2 To meet the requirements of Rule 27(1)(b) EPC, the document D1 (DE4124778) should be identified in the description and its relevant contents should be indicated. The applicant should ensure that it is clear from the description which features of the subject-matter of independent claims are known from this document.

1.3 Preferably, the amended independent claims should be framed in the two-part form (R29(1) EPC), with those features known in combination from D1 being placed in the preamble.

1.4 The summary of the invention should be adapted to the amended claims (Art 84 EPC).

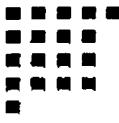
EXHIBIT B
PAGE 2 OF 2

Select Continent

[中文](#) | [English](#) | [Español](#) | [Français](#) | [Deutsch](#) | [Italiano](#) | [Sitemap](#)

[日本語](#) | [한국어](#) | [Nederlands](#) | [Português](#) | [русский](#)

Global Home >> Filtration >> Fabrics & Media

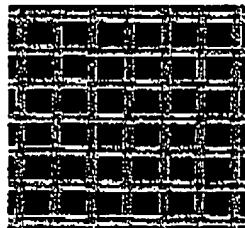


SEFAR

Contact
Fabric Finder
Industries
Fabrication
Fabrics & Media
Open mesh
Filter fabrics
Specialties
Direct Access
Sefar News
Legal Disclaimer

Fabrics & Media

Sefar offers a huge range of different monofilament fabrics, using 15 kind of materials. Diameter ranges from 28 to 1000 µm. Regarding construction, we divide them into three groups: - Open mesh fabrics - Filter fabrics (closed mesh fabrics) - Specialties



Open mesh fabrics

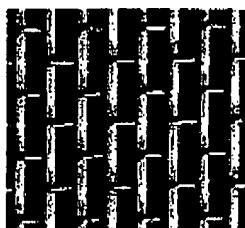
Sefar produces approx. 1'400 different open mesh monofilament fabrics with following materials:

- PA, PET, PP, ETFE, PEEK



Filter fabrics

Filter fabrics are mainly made of monofilament yarns. In order to provide a complete range, we also use multifilament and staple fibres.



Specialties

In this group we put all fabrics with special characteristics, such as antistatic or shrinkable fabrics.

News & P

- [New F](#)
- [Exhibit](#)

Additional In

Services

- [Diction](#)
- [Glossa](#)
- [Conver](#)
- [Mesh c](#)
- [How to](#)

[Top](#)

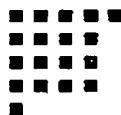
[send.page](#) | [print.page](#)

EXHIBIT C
PAGE 1 OF 6

Select Continent


[中文](#) | [English](#) | [Español](#) | [Français](#) | [Deutsch](#) | [Italiano](#) | [Sitemap](#)
[日本語](#) | [한국어](#) | [Nederlands](#) | [Português](#) | [русский](#)

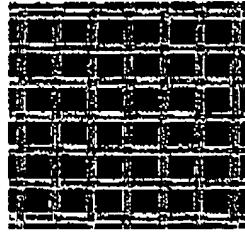
Global Home >> Filtration >> Fabrics & Media >> Open mesh



SEFAR

[Contact](#)[Fabric Finder](#)[Industries](#)[Fabrication](#)[Fabrics & Media](#)[Open mesh](#)[NITEX](#)[PETEX](#)[PROPYLTEX](#)[FLUORTEX](#)[PEEKTEX](#)[NYTAL](#)[MEDIFAB](#)[Filter fabrics](#)[Specialties](#)[Direct Access](#)[Sefar News](#)[Legal Disclaimer](#)

Open mesh fabrics



SEFAR NUTEX

Polyamide (PA) monofilament precision fabrics

SEFAR PETEX

Polyester (PET) monofilament precision fabrics

SEFAR PROPYLTEX

Polypropylene (PP) monofilament precision fabrics

SEFAR FLUORTEX

ETFE monofilament precision fabrics

SEFAR PEEKTEX

PEEK monofilament precision fabrics

SEFAR NYTAL

PA und PET precision fabrics for flour milling

SEFAR MEDIFAB

PA and PET precision fabrics for the medical industry

News & P

- [New F](#)
- [Exhibit](#)

Additional In

Services

- [Diction](#)
- [Glossa](#)
- [Conver](#)
- [Mesh_c](#)
- [How to](#)

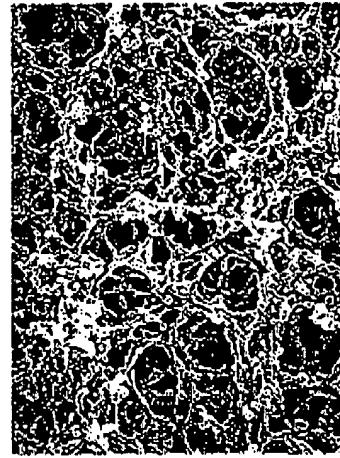
[▲ Top](#)[send page](#) | [print page](#)



[MEMBRANE DISC FILTERS](#) [HOME](#) [PRODUCTS](#) [FAQ](#) [ABOUT US](#) [NEWS](#) [CONTACT US](#)

Sterlitech Cellulose Acetate (CA) Membrane

[ORDERING INFO](#)



Sterlitech™ Cellulose Acetate Membrane

Sterlitech CA (Cellulose Acetate) membrane filters are composed of pure cellulose acetate modified to offer researchers the lowest binding filters available. Due to the extremely low binding characteristics, these filters provide higher throughputs than competitive offerings and reduce filter changes when filtering proteinaceous solutions.

Because of their unique strength and extremely low binding characteristics, Sterlitech CA (Cellulose Acetate) filters are ideal for protein and enzyme filtrations, tissue culture media sterilization, cold sterilization, biological fluid filtration and other filtration applications where maximum recovery of proteins is critical.

Ceramic Membranes and Disc Holders
Glass Fiber
Nitrocellulose Mixed Esters (NCE)
Polycarbonate (PCF)
Polyethersulfone (PES) Membrane
Polyester (PETE)
Polypropylene
Polypropylene Pre-Filters
PTFE (Teflon) Laminated
PTFE (Teflon) Unlaminated

FILTER HOLDERS

BENCH SCALE TEST EQUIPMENT

REQUEST INFORMATION

SEARCH OUR SITE

Features and Benefits:

- Lowest binding material available
- Hydrophilic



- High throughout
- Strength and dimension stability
- Uniform pore structure

Applications:

- Protein and enzyme filtration, sterilization
- Biological fluid filtration sterilization
- Tissue culture media sterilization
- Diagnostic cytology
- Receptor binding studies
- Enhanced recovery of fastidious gram positive organisms

[Click here to view the Membrane Compatibility Chart.](#)

Cellulose Acetate Membrane Product & Performance.
Cellulose Acetate Membrane Ordering Information.

**SteriTech
Corporation**

22027 70th Ave. S
Kent, WA
98032-1911 USA
Tel: 877-544-4420
253-437-0844
Fax: 253-437-0845
Info@SteriTech.com

[Home](#) | [Products](#) | [FAQ](#) | [About Us](#) | [News](#) | [Contact Us](#)

To order, call today: 1-877-544-4420
Or email: sales@SteriTech.com
Free eNewsletter!

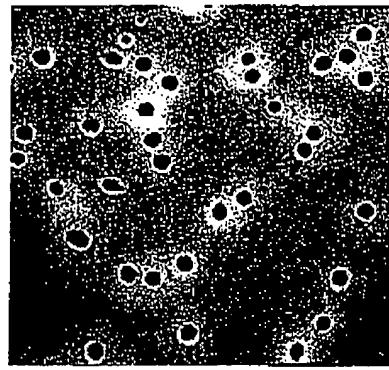
© 2002 SteriTech Corporation. All rights reserved. Contact Info@SteriTech.com. Website: [MetaToggle](http://www.SteriTech.com)



[HOME](#) [PRODUCTS](#) [FAQ](#) [ABOUT US](#) [NEWS](#) [CONTACT US](#)

Sterlitech Polycarbonate Track Etch (PCTE) Membranes

[ORDERING INFO](#)



Polycarbonate Track Etch (PCTE) membrane is made from a thin, microporous polycarbonate film material. It is ideally suited for use in blood assays and high-purity and general filtration.

Precise pore size and density

PCTE membrane is produced through a two-step, proprietary manufacturing process that employs high quality standards. This unique process allows for increased control over pore size and density to ensure the physical properties of each membrane precisely fit your specifications.

In the first step, thin polycarbonate film is exposed to collimated, charged particles from a nuclear pile. As these particles pass through the polycarbonate material, they leave sensitized tracks. In the second, step the polymer tracks are dissolved with an etching solution to form cylindrical pores. Varying the temperature and strength of the etching solution, and the exposure time to it, produces precisely controlled pore sizes.

The resulting membrane is a thin, translucent and microporous polycarbonate film with a smooth, flat surface. All particles larger than the pore size are captured on its surface. It is ideal for use when collecting samples for blood assays or for high-purity and general filtration.

Features and Benefits (Click for details):

- Absolute pore size and density
- Smooth, thin, glass-like surface

[BENCH SCALE TEST EQUIPMENT](#)

[REQUEST INFORMATION](#)

[SEARCH OUR SITE](#)

EXHIBIT C

- Superior strength
- Low extractables
- Low protein binding
- Negligible absorption/adsorption
- Available as hydrophilic or hydrophobic

[Click here to view the Membrane Compatibility Chart.](#)

[PCTE Membrane Features, Benefits and Applications.](#)
[PCTE Membrane Product & Performance.](#)
[PCTE Membrane Price & Size Information.](#)

[PCTE Membrane FAQ.](#)

**Sterlitech
Corporation**

22027 70th Ave. S
Kent, WA
98031-1911 USA
Tel: 877-544-4420
253-437-0844
Fax: 253-437-0845
Info@Sterlitech.com

[Home](#) | [Products](#) | [FAQ](#) | [About Us](#) | [News](#) | [Contact Us](#)

To order, call today: 1-877-544-4420
Or email: sales@Sterlitech.com
[Free eNewsletter!](#)

© 2002 Sterlitech Corporation. All rights reserved. Contact info@Sterlitech.com. Website: [MetaToggle](#)



[HOME](#)
[PREMIUM SERVICES](#) ▾

[M-WCollegiate.com](#)
[M-WUnabridged.com](#)
[Britannica.com](#)
[Multi-User Licenses](#)

[DOWNLOADS](#) ▾
[WORD OF THE DAY](#) ▾
[WORD GAMES](#) ▾
[WORD FOR THE WISE](#) ▾
[ONLINE STORE](#) ▾
[HELP](#) ▾

[Merriam-Webster Inc.](#)
[Company information](#)

Merriam-Webster Online Dictionary

nonwoven

One entry found for **nonwoven**.

Main Entry: **non·wo·ven**

Pronunciation: -'wō-vən

Function: *adjective*

1 : made of fibers held together by interlocking or bonding (as by chemical or thermal means) : not woven, knitted, or felted *<nonwoven fabric>*
 2 : made of nonwoven fabric *<a nonwoven dress>*
 - *nonwoven noun*

For [More Information on "nonwoven" go to Britannica.com](#)

Get the [Top 10 Search Results for "nonwoven"](#)

Ads by Google

[Industry Nonwovens](#)

Industry Nonwovens since 1989 Spunbonded Polypropylene Nonwovens
www.texbondspa.com

[Innovatec Microfibre](#)

produces melt-blown nonwovens produziert melt-blown Vliese
www.melt-blown.com

[All nonwoven fabrics](#)

spunbond, spunlace, needlepunch.5-206 inch rolls, perf. sheets
www.oxco.com

[Merriam-Webste](#)

[Dictionary](#)

[Thesaurus](#)

[Thesaurus](#)

[Browse by letter](#)

[A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#)

[N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#)

[Browse words n](#)

[nonwoven](#)



nonwoven

[Babylon-Pro](#)

Get instant results
 Merriam-Webster i
 desktop application
 single click

[Merriam-Web
Babylon-Pro](#)

[Handheld Collegiate](#)

Now you can take
 Eleventh Edition w
 anywhere as Franklin
 new Speaking Electronic
 Handheld!

[Franklin.com/](#)

[Merriam-Web
Collegiate
14-day Free](#)

EXHIBIT D
 PAGE 1 OF 1